**ASSOCIATION FOR MOLECULAR PATHOLOGY**
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June 10, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1808-P, P.O. Box 8013
Baltimore, MD 21244-8013.

Submitted electronically at https://www.regulations.gov

Re: Proposed Rule on Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the LongTerm Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes (RIN: 0938–AV34)

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to the Proposed Rule on Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the LongTerm Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes ("the IPPS proposed rule"). AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

**F. CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses**

The proposed rule mandates hospitals and critical access hospitals (CAHs) to electronically report information on COVID-19, influenza, and RSV infections among in-patients, as well as hospital bed capacity and occupancy rates on a weekly basis through a CDC-owned or supported system beginning on October 1, 2024. This will include a standardized format to be specified by the Secretary. These reporting requirements were in place during the COVID-19 public health emergency (PHE) and expired on April 30th, 2024. During the preceding four years, AMP members experienced a significant resource burden in complying with these unfunded reporting requirements, which was further compounded by the ongoing laboratory workforce shortages. AMP is concerned that extending reporting requirements as outlined in the IPPS proposed rule will place an undue burden on laboratories that are not justified outside of a declared PHE.

In 2020, AMP surveyed its membership to understand the laboratory community's response to the pandemic including challenges encountered.[1] Data from that survey, combined with information discussed within the Centers for Disease Control and Prevention's (CDC) Clinical Laboratory Partners network and on CDC COVID-19

[1] https://www.amp.org/advocacy/sars-cov-2-survey/

response calls, revealed significant challenges with laboratory capability to provide data to public health agencies. At the time of the survey, respondents relayed that they were currently reporting to multiple state or federal agencies or departments. Approximately 75% of respondents reported that at the time, their laboratory spent up to two hours per day complying with public health reporting requirements, with almost half of the respondents stating that they found the current multiple public health reporting requirements burdensome.[2] Survey respondents expressed frustration that reporting is not standardized across the nation, and that information is required to be submitted to multiple local, state, and federal locations.

During the COVID-19 PHE, AMP members also encountered data systems limitations that created additional challenges with compliance with the federal reporting requirements in place at the time. Examples of some challenges included that most laboratory information systems (LIS) do not have a place to assign unique device identifiers in its database, HL7 electronic reporting to government agencies was not available, and that LOINC/SNOMED previously were not required and the LIS didn't have a place to assign these in its database.[3]

Based on the experience of our members during the pandemic, AMP recommends that the federal government standardizes agency reporting format and processes for reportable infectious diseases during a PHE and proactively solicits advice and recommendations from the clinical laboratory community before requiring reporting in the absence of a PHE, including:

1. Define minimal required data elements for supporting public health contact tracing.
2. Establish standardized reporting format that electronic health records (EHR) / laboratory information system (LIS) vendors could adopt.
3. Establish a standardized reporting agency / process that minimizes delays in return of results and eliminates need for laboratories to duplicate reporting to multiple agencies.
4. Provide logistical support for laboratories to provide reportable infectious disease data electronically.

The proposed rule states that the CDC, Centers for Medicare and Medicaid Services (CMS), and the Administration for Strategic Preparedness and Response (ASPR) are working with the Office of the National Coordinator for Health Information Technology (ONC) to establish national standards and interoperability requirements that reduce burden and promote standardization in data reporting. AMP requests that this work be completed and also harmonized with state and local reporting requirements before mandating any additional reporting during times of non-emergency to minimize the burden on laboratories. Additionally, we request that clinical laboratory experts from private, hospital, regional- and national reference laboratories be included in the process to advise on real-world experience and limitations that could impact the process. This will also help ensure that the challenges to comply with data reporting experienced during the COVID-19 pandemic are addressed and thus, enable easier compliance with any new data reporting requirements in the future.

Thank you for the opportunity to provide these comments for your consideration. AMP strongly recommends delaying any reporting requirements for respiratory diseases during a non-PHE time until a clear process that leverages existing EHR systems is in place to minimize the burden on laboratories.

Sincerely,

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2 https://www.amp.org/AMP/assets/File/advocacy/AMP%20Future%20Pandemic%20White%20Paper%20Response.pdf?pass=52

3 https://www.amp.org/AMP/assets/AMP%20Comments-CMS%20IFR-LabReporting-CMS-3401-IFC-FINAL-11-2-20.pdf?pass=60

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